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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

ORTHO-MCNEIL JANSSEN PHARMACEUTICALS, INC.,	)	Civil Action No.
Plaintiff,	)	
vs.	)	
AMNEAL PHARMACEUTICALS,	)	
Defendant.	)	

COMPLAINT

In this patent infringement action, Plaintiff Ortho-McNeil Janssen Pharmaceuticals, Inc., for its complaint against Defendant Amneal Pharmaceuticals, alleges as follows:

PARTIES

1. Plaintiff Ortho-McNeil Janssen Pharmaceuticals, Inc. ("Ortho-McNeil") is a corporation incorporated under the laws of the State of Pennsylvania with its principal place of business at 1125 Trenton-Harbourton Road, Titusville, New Jersey 08560.

2. Upon information and belief, Defendant Amneal Pharmaceuticals ("Amneal") is a New Jersey corporation with its principal place of business at 209 McLean

Boulevard, Paterson, New Jersey 07504.

JURISDICTION AND VENUE

3. This action for patent infringement arises under 35 U.S.C. § 100 *et seq.* generally, and 35 U.S.C. § 271(e)(2) specifically.

4. This Court has subject matter jurisdiction over this dispute pursuant to 28 U.S.C. §§ 1331 and 1338.

5. Amneal is subject to personal jurisdiction in this district.

6. Venue is proper in this district pursuant to 28 U.S.C. §§ 1391(b) and (c) and 1400.

GENERAL ALLEGATIONS

7. On August 1, 2006, the United States Patent and Trademark Office ("USPTO") granted Reissue Patent No. RE39,221 ("the RE221 Patent"). A true and correct copy of the RE221 Patent is attached as Exhibit A.

8. Ortho-McNeil is the current assignee of the RE221 Patent.

9. Ortho-McNeil owns all rights, title, and interest in the RE221 Patent.

10. Ortho-McNeil markets the drug covered by New Drug Application ("NDA") No. 21-123 under the tradename Ultracet®, the active ingredients of which are tramadol hydrochloride and acetaminophen (hereinafter, "Ultracet®" or "the Ultracet® drug product").

11. On information and belief, Amneal is a New Jersey corporation that manufactures generic pharmaceuticals in the United States.

12. On information and belief, Amneal has filed Abbreviated New Drug Application ("ANDA") No. 90-485 with the Food and Drug Administration ("FDA") for

approval to engage in the commercial manufacture, sale, or offer for sale of a therapeutic composition containing tramadol hydrochloride and acetaminophen.

13. On information and belief, Amneal's ANDA No. 90-485 contains a certification under § 505(j)(2)(A)(vii)(IV) of the FDCA (codified at 21 U.S.C. § 355(b)(2)(A)(iv)) ("the Paragraph IV Certification") asserting that the RE221 Patent is invalid or will not be infringed and seeks approval to engage in the commercial manufacture, use, sale, or offer for sale of a pharmaceutical composition containing acetaminophen and tramadol hydrochloride at a dosage ratio of 325 mg/37.5 mg in oral tablets prior to the expiration of the RE221 Patent.

14. Amneal notified Ortho-McNeil of this certification via a letter bearing the date July 25, 2008 ("Paragraph IV notice").

15. Upon information and belief, Amneal has not received tentative approval of its ANDA No. 90-845.

16. According to the Paragraph IV notice bearing the date July 25, 2008, Amneal asserts that its tramadol hydrochloride/acetaminophen product would not infringe claims 6, 15, 21, 23, 25-26, 28-29, 37-38, 40-41, 49-50, 52-53, 55-66, 70-71, 73, and 75-76 of the RE221 Patent. The Paragraph IV notice bearing the date July 25, 2008 does not contest infringement of the remaining claims of the RE221 Patent by Amneal's product as detailed in ANDA No. 90-845. According to the Paragraph IV notice, Amneal contends that all of the RE221 Patent claims are invalid as obvious or anticipated.

17. The RE221 Patent is the end result of a reissuance process that began on January 20, 2004 when Ortho-McNeil Pharmaceutical, Inc. filed an application with the USPTO to reissue U.S. Patent No. 5,336,691 ("the '691 patent"), issued August 9, 1994.

18. During the course of the reissue proceedings, Ortho-McNeil Pharmaceutical, Inc. provided the PTO with the prior art and arguments made by other generic manufacturers in the course of earlier-filed cases involving the '691 patent. During the course of the reissue proceedings, Ortho-McNeil Pharmaceutical, Inc. likewise provided the PTO with both U.S. Patent No. 3,652,899 (also known as the Flick patent) and Brinkmann, J., Analgetikatherapie bei Tumorpatienten in der Praxis, ZFA Z. Allg. Med. 65:166-68 (1989), the only two prior art references relied upon by Amneal in its Paragraph IV Certification.

19. On April 4, 2007, a New Jersey district court issued an opinion on summary judgment in consolidated Cases No. 02-5707 and 04-0886, ruling that claim 6 of the RE221 Patent was infringed by defendant Barr Pharmaceuticals but was invalid.

20. On April 17, 2008, a New Jersey district court issued an opinion on summary judgment in consolidated Cases No. 04-0886 and 06-3553, ruling that other claims (claims 43-48, 51, 54, 67, 69, 72 and 74) of the RE221 Patent were invalid.

21. On May 8, 2008, an Illinois district court granted judgment in Case No. 08 C 1343 in favor of generic manufacturers, Mylan Pharmaceuticals Inc. and Alphapharm, based on the collateral estoppel effect of the New Jersey court's decision in Case No. 06-3533. This judgment was granted one day after Ortho-McNeil Pharmaceutical, Inc. notified the court that it did not oppose judgment on this basis, while reserving its right to reopen the case under Federal Rule of Civil Procedure 60(b)(5) if and when the U.S. Court of Appeals for the Federal Circuit reverses the underlying summary judgment decision.

22. In another case, No. 07-4050 (N.D. Ill.), Ortho-McNeil Pharmaceutical, Inc. has stated that it has no objection to a judgment in favor of defendant Apotex, Inc. on the basis of the collateral estoppel effect of the summary judgment decisions issued by the New

Jersey district court. (*See, e.g.*, Case No. 07-4050, N.D. Ill., Docket No. 96.)

23. On August 25, 2008, Ortho-McNeil Pharmaceutical, Inc. filed a notice appealing both the April 4, 2007 and April 17, 2008 summary judgment decisions in the New Jersey consolidated cases. Ortho-McNeil maintains that the New Jersey district court erred in invalidating claims of the RE221 Patent.

24. Given the district court's April 17, 2008 decision and the pending appeal, if Amneal requests the entry of judgment in its favor based on the collateral estoppel effect of the April 17, 2008 summary judgment decision, Ortho-McNeil would have no objection, subject to Ortho-McNeil's reservation of its right to reopen the case under Federal Rule of Civil Procedure 60(b)(5) if and when the U.S. Court of Appeals for the Federal Circuit reverses that decision. The complaint is filed at this time to fully protect Ortho-McNeil's right to obtain the statutory 30-month stay of FDA approval of Amneal's ANDA No. 90-485 if and when the U.S. Court of Appeals for the Federal Circuit reverses the court's April 17, 2008 summary judgment of invalidity.

COUNT I

25. Ortho-McNeil incorporates and realleges Paragraphs 1 through 24 above, as if set forth in full herein.

26. Because Amneal seeks approval of ANDA No. 90-845 and, on information and belief, with such approval seeks to engage in the manufacture, use, offer for sale, import, or sale of the pharmaceutical composition and its method of use claimed by the RE221 Patent before that patent's expiration, Amneal has infringed one or more claims of the RE221 Patent pursuant to 35 U.S.C. § 271(e)(2)(A), entitling Ortho-McNeil to the relief provided by 35 U.S.C. § 271(e)(4), including, *inter alia*, an order of this Court that the effective date of approval for Amneal's ANDA be a date which is not earlier than the expiration date of the

RE221 Patent, a date which is currently September 6, 2011.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff Ortho-McNeil requests that:

A. If Amneal requests the entry of judgment in its favor based on the collateral estoppel effect of the April 17, 2008 summary judgment decision, judgment be entered, subject to Ortho-McNeil's reservation of its right to reopen the case under Federal Rule of Civil Procedure 60(b)(5) if and when the U.S. Court of Appeals for the Federal Circuit reverses that decision.

B. If and when the U.S. Court of Appeals for the Federal Circuit reverses the April 17, 2008 summary judgment decision,

1. Judgment be entered that Amneal has infringed one or more claims of the RE221 Patent;

2. Judgment be entered that the manufacture, use, sale, or offer to sell within the United States, or importation into the United States of the generic copy of Ultracet® described in Amneal's ANDA No. 90-845 infringes one or more claims of the RE221 Patent;

3. An order be entered directing the FDA not to approve Amneal's ANDA No. 77-858 any earlier than the expiration date of the RE221 Patent;

4. A permanent injunction be granted preventing Amneal, its officers, directors, agents, attorneys, employees, successors and assigns, and those acting in privity or concert with it from engaging in the commercial manufacture, use, offer to sell, or sale within

the United States, or importation into the United States of a pharmaceutical composition claimed in the RE221 Patent prior to the expiration of the RE221 patent;

5. Ortho-McNeil be awarded its costs and expenses in bringing and prosecuting this action; and

6. Ortho-McNeil be granted such other and further relief as the Court may deem just and proper.

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Respectfully submitted,

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